

Serial No.: 10/580,979

Confirmation No.: 9290

371(c) Filing Date: April 9, 2007

For: REPLICATION COMPETENT HEPATITIS C VIRUS AND METHODS OF USE

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**Remarks**

The Office Action mailed September 28, 2010 has been received and reviewed. Claims 1, 14, 18, 26, 33 and 53 having been amended, the claims 1-4, 6-8, 14-24, 26-31, 33-35, 41-43, and 47-53 are pending. Reconsideration and withdrawal of the rejections are respectfully requested.

An Interview was conducted on October 28, 2010, between Examiner Bao Li and Applicant's Representative David Provence. The statements provided by the Examiner in the interview summary, mailed November 8, 2010, form a complete and accurate record of this interview. The rejections under §112, second paragraph, were discussed. No agreement was reached.

Support for the amendment of the claims to include "of the polyprotein" may be found throughout the claims as originally filed and in the specification at, for example, page 16, lines 5 through 15.

**The 35 U.S.C. §112, Second Paragraph, Rejection**

MPEP §2173 sets forth the purposes of the requirements of 35 U.S.C. §112, second paragraph:

The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability[.]

M.P.E.P. §2173.02 reinforces the primary purpose of 35 U.S.C. §112, second paragraph, that is set forth immediately above:

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. (emphasis added).

**The first rejection under 35 U.S.C. 112, second paragraph**

The Examiner has maintained the rejection of claims 1-5, 6-8, 14-24, 26-31, 33-35, 41-43, and 47-52 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The traversal of this rejection is respectfully maintained. In addition to remarks made in the replies dated June 9, 2009, December 17, 2009, and August 17, 2010, consideration of the following is requested.

At paragraph 4 of the Office Action the Examiner alleges that the claims remain rejected under 35 U.S.C. 112, second paragraph, "because from where the numeric number [sic] of the mutated amino acid(s) need to be defined." The independent claims have been amended to include "of the polyprotein" immediately following each recitation of the location of an adaptive mutation.

Applicants respectfully submit that a person of skill in the art would understand how to determine if an adaptive mutation is present. A person of ordinary skill in the art of molecular biology is well aware of how to determine the location of the adaptive mutations recited in the claims. The U.S. Supreme Court, in *KSR International v. Teleflex*, has stated, "A person of ordinary skill is also a person of ordinary creativity, not an automaton." 82 USPQ2d 1385, 1397. Given that a person of ordinary skill is not an automaton, the skilled person with at least a modicum of common sense is fully capable of using specification at, for instance, page 13, line 12 through page 14, line 6, and page 16, lines 5 through 15, and the knowledge generally available at the time the application was filed to determine the locations of the recited adaptive mutations in the claimed polynucleotides.

Reconsideration and withdrawal of this rejection is respectfully requested.

**The second rejection under 35 U.S.C. 112, second paragraph**

The Examiner made a new ground of rejection under 35 U.S.C. 112, second paragraph, rejecting claims 1, 14, 18, 24, and 33, allegedly because the claims use the word "about" to define the positions of mutations. This rejection is respectfully traversed.

A claim is not automatically rendered indefinite just because it includes language, such as terms of degree, that is not precise. MPEP §2173(b). Whether claim language is acceptable depends on “whether one of ordinary skill in the art would understand what is claimed, in light of the specification.” MPEP §2173(b). When a claim includes a term of degree, the Office must determine whether there is some standard for measuring that degree in the specification. MPEP §2173(b).

The term “about” is a term of degree present in the pending claims. For example, the independent claims recite, *inter alia*, “wherein the adaptive mutations comprise an isoleucine at about amino acid 2204” (emphasis added). The specification shows at Table 2, page 16, the locations of the claimed adaptive mutations, and goes on to state the following:

“A person of ordinary skill in the art recognizes that the precise location of these cell culture adaptive mutations can vary between . . . members of the same genotype, thus the numbers shown in Table 2 are approximate, and can vary by 1, 2, 3, 4, or about 5.”

Specification at page 16, lines 5-8. The specification clearly includes a standard for measuring what the term “about” means in the context of the location of adaptive mutations in a polyprotein. The skilled person would understand, in light of the specification, what the term “about” means, and consequently what is claimed. Since the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent, the claims comply with the requirements of 35 U.S.C. 112, second paragraph.

Reconsideration and withdrawal of the rejection of claims 1, 14, 18, 24, and 33 under 35 U.S.C. 112, second paragraph, is respectfully requested.

**The third rejection under 35 U.S.C. 112, second paragraph**

The Examiner also rejected claims 1, 18, 24, and 33 under 35 U.S.C. 112, second paragraph, allegedly because the number of mutations in present in the polypeptide is unclear. This rejection is respectfully traversed.

The Examiner is respectfully requested to note the following language in claim 1:

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“An isolated polynucleotide . . . comprising: . . . a first coding sequence . . . encoding a hepatitis C virus polyprotein, . . . wherein the amino acid sequence of the polyprotein comprises at least three adaptive mutations, wherein the adaptive mutations comprise an isoleucine at about amino acid 2204 and at least two adaptive mutations selected from the group of [6 different adaptive mutations], and a combination thereof.”

Claim 1, emphasis added. Similar language is present in the other independent claims included in this rejection. The claim clearly states there are at least three adaptive mutations in a claimed polyprotein. The claim also clearly states that the first adaptive mutation is an isoleucine at about residue 2204, and that the other two adaptive mutations are selected from the 6 other mutations listed in the claim. There is no language in the claim that would lead the skilled person to believe that the “at least two adaptive mutations” are excluded as alleged in the rejection at paragraph 9 of the Office Action. Applicants respectfully submit that no person of skill in the art would be confused as to the number of adaptive mutations that can be present in a polypeptide described in the claims.

Reconsideration and withdrawal of the rejection of claims 1, 18, 24, and 33 under 35 U.S.C. 112, second paragraph, is respectfully requested.

**Amendment and Response**

Page 14 of 14

Serial No.: 10/580,979

Confirmation No.: 9290

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**Summary**

It is respectfully submitted that the pending are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted  
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December 23, 2010  
Date

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**CERTIFICATE UNDER 37 CFR §1.6:**

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 23<sup>rd</sup> day of December, 2010.

By: Dani Monroe  
Name: Dani Monroe

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